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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,861	12/26/2001	Hai Xing Chen	99,003.1	4882

7590 10/28/2005

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,861

Applicant(s)

CHEN, HAI XING

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 15, 2005 has been entered.

Status of the Application

2. The action is in response to the RCE filed on August 15, 2005. Currently claims 1-25 are pending. Claims 26-29 are cancelled. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in view of the amendment.

Priority

3. The instant application filed on December 26, 2001 is a CIP of US non-provisional 09/326,297 filed on 6/4/1999 now PAT 6,337,214, which is a CIP of 09/093,532 filed on 6/8/1998, now PAT 6,174,733.

4. Claim interpretation: In the following rejection, test column is given broadest reasonable interpretation as an array and snare as a defined spot or location of capture material or target, and the term "sequential" is not defined in the instant specification and Applicants refer Figs 6-12 for the basis of the term "sequential" thus the term "sequential" is interpreted as a process having different steps and addition of reaction components at different times during the process.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1637

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 1-4, 6-16, 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac et al. (USPN. 6,297,006) and in view of Muller et al. (USPN. 5,804,384).

Drmanac et al. teach a method of claims 1, 7, 14, 18, 24, for sequentially detecting multiple test materials in a test sample comprising (a) adding a test sample in to a test column (small array with multiple target sequences) having a plurality of snares (subarrays) of said snares having multiple capture materials (capture sequences to multiple individual target sequences) (see col. 3, line 64-67, col. 4, line 1-18, col. 20, line 29-59),

(c) adding a probe with a chemical label (labeled probe) that specifically binds to the said first test material (see col. 4, line 19-20, col. 20, line 64-67, col. 21, line 1-5);

(d) washing said test column to remove unbound probes (see col. 21, line 5-11);

(e) detecting the signals generated by said chemical label and determining the presence of the first test material (see col. 4, line 21-22, col. 21, line 20-28);

(f) adding a second labeled probe to attach to a second test material (see col. 4, line 23-25);

(g and h) washing and detecting signals generated by remaining probes and detecting multiple test materials (see col. 4, line 24-31).

With regard to claims 1-2, 4, 7-9, Drmanac et al. teach multiple labels (two to six probes each having a different label) with triggering solution (see col. 5, line 30-36, col. 15, line 52-65);

With regard to claims 3, 16, 25, Drmanac et al. also teach said labels are chemiluminescence labels (BAP) (see col. 15, line 38-65);

With regard to claim 6, 15, 25, Drmanac et al. teach that the test material comprises DNA (see col. 3, line 64-65);

With regard to claims 10-13, 19-23, Drmanac et al. also teach said method comprises several control DNAs which include positive and negative controls (see col. 21, line 28-35).

However Drmanac et al. did not teach plurality of snares spaced apart along a longitudinal axis of said test column separated one from another by an intervening air space (linear arrays).

Muller et al. teach a method for detecting multiple analytes in a sample using linear arrays comprising capture probes (see abstract and col. 1, line 45-52, col. 3, line 9-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting multiple target nucleic acids as taught by Drmanac et al. with the step of including a channel or tube containing linear arrays as taught by Muller et al. to achieve expected benefit of developing a sensitive and automated method for simultaneously detecting multiple target sequences in a sample because Muller et al. explicitly taught the use of a tube containing linear array of probes that requires only small sample and reagent volumes and provides rapidly adaptable method to automation and increased sensitivity and avoids enzymatic amplification such as use of PCR (see col. 3, line 14-24). An ordinary practitioner would have been motivated to modify the method of detecting a target nucleic acids as taught by Drmanac et al. by incorporating the linear arrays as taught by Muller et al. to develop a sensitive and rapid method adaptable to automation which utilizes small volumes of sample and reagents and such modification of the method is considered obvious in the absence of secondary considerations.

B. Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac et al. (USPN. 6,297,006) and in view of Muller et al. (USPN. 5,804,384) as applied to claims 1-4, 6-16, 18-25 above, and further in view of Patel et al. (USPN. 5, 945,249).

Drmanac et al. in view of Muller et al. teach a method for sequentially detecting multiple test materials as discussed above in section 5A.

However neither Drmanac et al. nor Muller et al. teach acridinium dye as a chemical label.

Patel et al. teach laser addressable thermal imaging media comprising photothermal converting dye in association with a heat-sensitive imaging system and a photoreducing agent for said dye (see col. 3, line 20-29). Patel also teach that said dyes include cationic dyes such as polymethine dyes, acridinium dyes , cyanine dyes etc. (see col. 5, line 66-67, col. 6, line 1-4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting multiple target nucleic acids using chemical labels as taught by Drmanac et al. in view of Muller et al. with the step of adding photo-thermal converting dyes as acridinium dyes as taught by Patel et al. to achieve expected benefit of developing a sensitive and improved method for detecting multiple target sequences in a sample because Patel et al. taught that the use of laser addressable thermal media comprising acridinium dyes, that would give rise to multi-color images by repeated transfer of colored donors and the transfer occurs with high sensitivity and resolution and heating the transferred image for relatively short periods at temperatures in excess of about 120 C causes curing and hardening , and hence an image of enhanced durability (see col.1, line 41-58, col. 14, line 1-5). An ordinary practitioner would have been motivated to modify the method of detecting a target nucleic acids as taught by Drmanac et al. in view of Muller et al. by incorporating the acridinium dye as

taught by Patel et al. to develop a sensitive method for the purpose of obtaining better resolution of colored images in a relatively short exposure time and such modification of the method is considered obvious in the absence of secondary considerations.

Response to arguments

6. With reference to the rejections maintained in the previous office action under obviousness-type double-patenting, Applicants arguments and submission of terminal disclaimers for patents 6,714,733 and 6,337,214 are fully considered and the rejections are withdrawn herein in view of the terminal disclaimers.

7. With reference to the rejection made in the previous office action under 35 USC 102(e) as anticipated by Drmanac et al., Applicants' arguments and amendment are fully considered and found persuasive and the rejection is withdrawn in view of the amendment and new grounds of rejections.

8. With reference to the rejection made in the previous office action under 35 USC 103(a) as being unpatentable over Drmanac et al. in view of Patel et al. , Applicants' arguments and amendment are fully considered and found persuasive and the rejection is withdrawn in view of the amendment and new grounds of rejections.

Conclusion

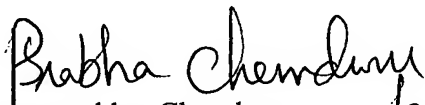
No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

Art Unit: 1637

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru 10/27/05
Patent Examiner
Art Unit 1637